US009198666B2

(12) **United States Patent**
Berez et al.

(10) **Patent No.: US 9,198,666 B2**
(45) **Date of Patent: *Dec. 1, 2015**

(54) **SYSTEM AND METHOD FOR DELIVERING AND DEPLOYING AN OCCLUDING DEVICE WITHIN A VESSEL**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 679 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **13/550,095**

(22) Filed: **Jul. 16, 2012**

(65) **Prior Publication Data**

US 2012/0283815 A1 Nov. 8, 2012

Related U.S. Application Data

(60) Continuation of application No. 12/420,383, filed on Apr. 8, 2009, now Pat. No. 8,236,042, which is a division of application No. 11/136,398, filed on May 25, 2005, now Pat. No. 8,147,534.

(51) **Int. Cl.**

A61F 2/06	(2013.01)
A61B 17/12	(2006.01)

(Continued)

(52) **U.S. Cl.**

CPC ***A61B 17/12022*** (2013.01); ***A61B 17/12118*** (2013.01); ***A61F 2/966*** (2013.01);

(Continued)

(58) **Field of Classification Search**

CPC ... A61B 17/12118; A61F 2/962; A61F 2/966; A61F 2/9665; A61F 2002/823; A61F 2/95; A61F 2002/9505–2002/9511; A61F 2002/9534; A61F 2002/9522

USPC 606/191, 192, 194, 195, 198; 623/1.11, 623/1.12

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,321,711	A	3/1982	Mano
4,503,569	A	3/1985	Dotter

(Continued)

FOREIGN PATENT DOCUMENTS

EP	418677	3/1991
EP	442657	8/1991

(Continued)

OTHER PUBLICATIONS

Hill, et al., "Initial Results of the Amplatzer Vascular Plug in the Treatment of Congenital Heart Disease, Business Briefing" US Cardiology, 2004.

(Continued)

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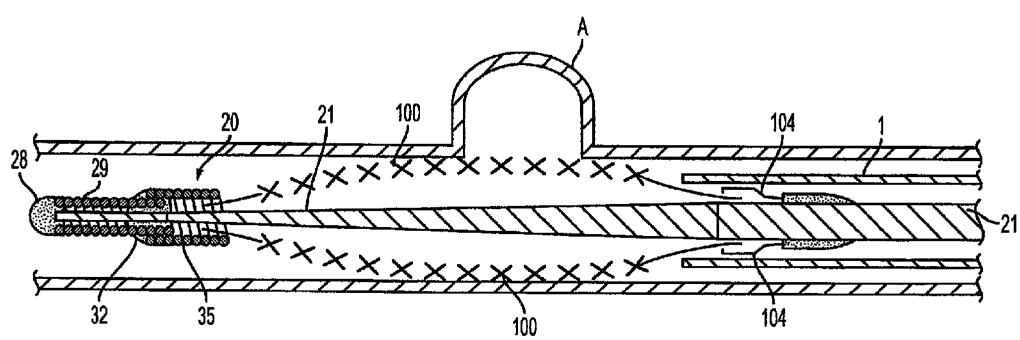
(57) **ABSTRACT**

A system and method for deploying an occluding device that can be used to remodel an aneurysm within the vessel by, for example, neck reconstruction or balloon remodeling. The system comprises an introducer sheath and an assembly for carrying the occluding device. The assembly includes an elongated flexible member having an occluding device retaining member for receiving a first end of the occluding device, a proximally positioned retaining member for engaging a second end of the occluding device and a support surrounding a portion of the elongated flexible member over which the occluding device can be positioned.

18 Claims, 9 Drawing Sheets



(51) **Int. Cl.**
A61F 2/966 (2013.01)
A61F 2/82 (2013.01)

(52) **U.S. Cl.**
CPC *A61B2017/1205* (2013.01); *A61B 2017/12054* (2013.01); *A61F 2002/823* (2013.01); *A61F 2002/9665* (2013.01)

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,512,338 A 4/1985 Balko et al.
4,538,622 A 9/1985 Samson et al.
4,580,568 A 4/1986 Gianturco
4,655,771 A 4/1987 Wallsten
4,733,665 A 3/1988 Palmaz
4,768,507 A 9/1988 Fischell et al.
4,776,337 A 10/1988 Palmaz
4,954,126 A 9/1990 Wallsten
4,998,539 A 3/1991 Delsanti
5,011,488 A 4/1991 Ginsburg
5,026,377 A 6/1991 Burton et al.
5,035,706 A 7/1991 Giantureo et al.
5,061,275 A 10/1991 Wallsten et al.
5,064,435 A 11/1991 Porter
5,108,416 A 4/1992 Ryan et al.
5,147,370 A * 9/1992 McNamara et al. 623/1.11
5,160,341 A 11/1992 Brenneman et al.
5,180,368 A 1/1993 Garrison
5,192,297 A 3/1993 Hull
5,201,757 A 4/1993 Heyn et al.
5,209,731 A 5/1993 Sterman et al.
5,222,971 A 6/1993 Willard et al.
5,242,399 A 9/1993 Lau et al.
5,246,420 A 9/1993 Kraus et al.
5,246,445 A 9/1993 Yachia et al.
5,334,210 A 8/1994 Gianturco
5,344,426 A 9/1994 Lau et al.
5,360,443 A 11/1994 Barone et al.
5,378,239 A 1/1995 Termin et al.
5,382,259 A 1/1995 Phelps et al.
5,401,257 A 3/1995 Chevalier, Jr. et al.
5,405,380 A 4/1995 Gianotti et al.
5,415,637 A 5/1995 Khosravi
5,421,826 A 6/1995 Crocker et al.
5,423,849 A 6/1995 Engelson et al.
5,445,646 A 8/1995 Euteneuer et al.
5,449,372 A 9/1995 Schmaltz et al.
5,458,615 A 10/1995 Klemm et al.
5,476,505 A 12/1995 Limon
5,480,423 A 1/1996 Ravenscroft et al.
5,484,444 A 1/1996 Braunschweiler et al.
5,489,295 A 2/1996 Piplani et al.
5,503,636 A 4/1996 Schmitt et al.
5,507,768 A 4/1996 Lau et al.
5,522,822 A 6/1996 Phelps et al.
5,534,007 A 7/1996 St. Germain et al.
5,545,209 A 8/1996 Roberts et al.
5,549,635 A 8/1996 Solar
5,562,641 A 10/1996 Flomenblit et al.
5,562,728 A 10/1996 Lazarus et al.
5,591,225 A 1/1997 Okuda
5,599,291 A 2/1997 Balbierz et al.
5,607,466 A 3/1997 Imbert et al.
5,609,625 A 3/1997 Piplani et al.
5,626,602 A 5/1997 Gianotti et al.
5,628,783 A 5/1997 Quiachon et al.
5,632,772 A 5/1997 Alcime et al.
5,636,641 A 6/1997 Fariabi
5,643,278 A 7/1997 Wijay
5,662,703 A 9/1997 Yurek et al.
5,667,522 A 9/1997 Flomenblit et al.
5,674,276 A 10/1997 Andersen et al.
5,683,451 A 11/1997 Lenker et al.
5,690,120 A 11/1997 Jacobsen et al.
5,690,644 A 11/1997 Yurek et al.
5,695,499 A 12/1997 Helgerson et al.
5,700,269 A 12/1997 Pinchuk et al.
5,702,418 A 12/1997 Ravenscroft
5,709,702 A 1/1998 Cogita
5,709,703 A 1/1998 Lukic et al.
5,725,552 A 3/1998 Kotula et al.
5,725,570 A 3/1998 Heath
5,725,571 A 3/1998 Imbert et al.
5,733,294 A 3/1998 Forber et al.
5,733,327 A 3/1998 Igaki et al.
5,735,859 A 4/1998 Fischell et al.
5,741,325 A 4/1998 Chaikof et al.
5,741,333 A 4/1998 Frid
5,749,883 A 5/1998 Halpern
5,749,891 A 5/1998 Ken et al.
5,749,919 A 5/1998 Blanc
5,749,920 A 5/1998 Quiachon et al.
5,769,884 A 6/1998 Solovay
5,769,885 A 6/1998 Quiachon et al.
5,776,099 A 7/1998 Tremulis
5,776,140 A 7/1998 Cottone
5,776,141 A 7/1998 Klein et al.
5,776,142 A 7/1998 Gunderson
5,782,909 A 7/1998 Quiachon et al.
5,797,952 A 8/1998 Klein
5,800,518 A 9/1998 Piplani et al.
5,807,398 A 9/1998 Shaknovich
5,810,837 A 9/1998 Hofmann et al.
5,814,062 A 9/1998 Sepetka et al.
5,817,102 A 10/1998 Johnson et al.
5,824,039 A 10/1998 Piplani et al.
5,824,041 A 10/1998 Lenker et al.
5,824,044 A 10/1998 Quiachon et al.
5,824,058 A 10/1998 Ravenscroft et al.
5,833,632 A 11/1998 Jacobsen et al.
5,836,868 A 11/1998 Ressemann et al.
5,846,261 A 12/1998 Kotula et al.
5,868,754 A 2/1999 Levine et al.
5,873,907 A 2/1999 Frantzen
5,888,201 A 3/1999 Stinson et al.
5,902,266 A 5/1999 Leone et al.
5,906,640 A 5/1999 Penn et al.
5,911,717 A 6/1999 Jacobsen et al.
5,916,194 A 6/1999 Jacobsen et al.
5,916,235 A 6/1999 Guglielmi
5,919,204 A 7/1999 Lukic et al.
5,925,060 A 7/1999 Forber
5,928,260 A 7/1999 Chin et al.
5,935,148 A 8/1999 Villar et al.
5,944,726 A 8/1999 Blaeser et al.
5,944,738 A 8/1999 Amplatz et al.
5,951,599 A 9/1999 McCrory
5,957,973 A 9/1999 Quiachon et al.
5,957,974 A 9/1999 Thompson et al.
5,964,797 A 10/1999 Ho
5,972,015 A 10/1999 Scribner et al.
5,980,530 A 11/1999 Willard et al.
5,980,533 A 11/1999 Holman
5,980,554 A 11/1999 Lenker et al.
5,984,929 A 11/1999 Bashiri et al.
6,014,919 A 1/2000 Jacobsen et al.
6,015,432 A 1/2000 Rakos et al.
6,017,319 A 1/2000 Jacobsen et al.
6,019,778 A 2/2000 Wilson et al.
6,019,786 A 2/2000 Thompson
6,022,369 A 2/2000 Jacobsen et al.
6,024,754 A 2/2000 Engelson
6,024,763 A 2/2000 Lenker et al.
6,027,516 A 2/2000 Kolobow et al.
6,033,423 A 3/2000 Ken et al.
6,036,720 A 3/2000 Abrams et al.
6,039,758 A 3/2000 Quiachon et al.
6,042,589 A 3/2000 Marianne
6,051,021 A 4/2000 Frid
6,056,993 A 5/2000 Leidner et al.
6,063,070 A 5/2000 Eder
6,063,104 A 5/2000 Villar et al.
6,063,111 A 5/2000 Hieshima et al.
6,068,634 A 5/2000 Lorentzen Cornelius et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,074,407 A 6/2000 Levine et al.
6,077,295 A 6/2000 Limon et al.
6,086,577 A 7/2000 Ken et al.
6,093,199 A 7/2000 Brown et al.
6,096,052 A 8/2000 Callister et al.
6,102,942 A 8/2000 Ahari
6,113,607 A 9/2000 Lau et al.
6,123,712 A 9/2000 Di Caprio et al.
6,123,715 A 9/2000 Amplatz
6,126,685 A 10/2000 Lenker et al.
6,132,459 A 10/2000 Piplani et al.
6,139,543 A 10/2000 Esch et al.
6,139,564 A 10/2000 Teoh
6,146,415 A 11/2000 Fitz
6,149,680 A 11/2000 Shelso et al.
6,152,144 A 11/2000 Lesh et al.
6,165,178 A 12/2000 Bashiri et al.
6,168,592 B1 1/2001 Kupiecki et al.
6,168,615 B1 1/2001 Ken et al.
6,168,618 B1 1/2001 Frantzen
6,168,622 B1 1/2001 Mazzocchi
6,183,410 B1 2/2001 Jacobsen et al.
6,190,402 B1 2/2001 Horton et al.
6,193,708 B1 2/2001 Ken et al.
6,197,046 B1 3/2001 Piplani et al.
6,206,868 B1 3/2001 Parodi
6,210,400 B1 4/2001 Hebert et al.
6,210,434 B1 4/2001 Quiachon et al.
6,210,435 B1 4/2001 Piplani et al.
6,214,038 B1 4/2001 Piplani et al.
6,214,042 B1 4/2001 Jacobsen et al.
6,221,086 B1 4/2001 Forber
6,221,102 B1 4/2001 Baker et al.
6,224,609 B1 5/2001 Ressemann et al.
6,224,829 B1 5/2001 Piplani et al.
6,231,597 B1 5/2001 Deem et al.
6,235,050 B1 5/2001 Quiachon et al.
6,241,758 B1 6/2001 Cox
6,241,759 B1 6/2001 Piplani et al.
6,245,103 B1 6/2001 Stinson
6,251,132 B1 6/2001 Ravenscroft et al.
6,260,458 B1 7/2001 Jacobsen et al.
6,261,305 B1 7/2001 Marotta et al.
6,270,523 B1 8/2001 Herweck et al.
6,280,465 B1 8/2001 Cryer
6,287,331 B1 9/2001 Heath
6,290,721 B1 9/2001 Heath
6,302,810 B2 10/2001 Yokota
6,302,893 B1 10/2001 Limon et al.
6,322,576 B1 11/2001 Wallace et al.
6,322,586 B1 11/2001 Monroe et al.
6,322,587 B1 11/2001 Quiachon et al.
6,331,184 B1 12/2001 Abrams
6,342,068 B1 1/2002 Thompson
6,344,041 B1 2/2002 Kupiecki et al.
6,344,048 B1 2/2002 Chin et al.
6,346,117 B1 2/2002 Greenhalgh
6,348,063 B1 2/2002 Yassour et al.
6,350,199 B1 2/2002 Williams et al.
6,350,270 B1 2/2002 Roue
6,350,278 B1 2/2002 Lenker et al.
6,355,061 B1 3/2002 Quiachon et al.
6,368,339 B1 4/2002 Amplatz
6,368,344 B1 4/2002 Fitz
6,368,557 B1 4/2002 Piplani et al.
6,371,928 B1 4/2002 Mcfann et al.
6,375,668 B1 4/2002 Gifford et al.
6,375,670 B1 4/2002 Greenhalgh
6,375,676 B1 4/2002 Cox
6,379,618 B1 4/2002 Piplani et al.
6,380,457 B1 4/2002 Yurek et al.
6,383,174 B1 5/2002 Eder
6,387,118 B1 5/2002 Hanson
6,391,037 B1 5/2002 Greenhalgh
6,395,017 B1 5/2002 Dwyer et al.
6,395,022 B1 5/2002 Piplani et al.
6,398,802 B1 6/2002 Yee
6,409,683 B1 6/2002 Fonseca et al.
6,413,235 B1 7/2002 Parodi
6,416,536 B1 7/2002 Yee
6,428,489 B1 8/2002 Jacobsen et al.
6,428,558 B1 8/2002 Jones et al.
6,432,130 B1 8/2002 Hanson
6,440,088 B1 8/2002 Jacobsen et al.
6,443,971 B1 9/2002 Boylan et al.
6,443,979 B1 9/2002 Stalker et al.
6,447,531 B1 9/2002 Amplatz
6,451,025 B1 * 9/2002 Jervis 606/108
6,454,780 B1 9/2002 Wallace
6,454,999 B1 9/2002 Farhangnia et al.
6,468,266 B1 10/2002 Bashiri et al.
6,478,778 B1 11/2002 Jacobsen et al.
6,482,221 B1 11/2002 Hebert et al.
6,491,648 B1 12/2002 Cornish et al.
6,503,450 B1 1/2003 Afzal et al.
6,506,204 B2 1/2003 Mazzocchi
6,511,468 B1 1/2003 Cragg et al.
6,514,261 B1 2/2003 Randall et al.
6,520,983 B1 2/2003 Colgan et al.
6,524,299 B1 2/2003 Tran et al.
6,527,763 B2 3/2003 Esch et al.
6,533,811 B1 3/2003 Ryan et al.
6,540,778 B1 4/2003 Piplani et al.
6,547,779 B2 4/2003 Levine et al.
6,547,804 B2 4/2003 Porter et al.
6,551,303 B1 4/2003 Van Tassel et al.
6,572,646 B1 6/2003 Boylan et al.
6,576,006 B2 6/2003 Limon et al.
6,579,303 B2 6/2003 Amplatz
6,582,460 B1 6/2003 Cryer
6,585,748 B1 7/2003 Jeffree
6,589,236 B2 7/2003 Wheelock et al.
6,589,256 B2 7/2003 Forber
6,589,265 B1 7/2003 Palmer et al.
6,589,273 B1 7/2003 McDermott
6,592,616 B1 7/2003 Stack et al.
6,599,308 B2 7/2003 Amplatz
6,602,280 B2 8/2003 Chobotov
6,605,102 B1 8/2003 Mazzocchi et al.
6,605,110 B2 8/2003 Harrison
6,605,111 B2 8/2003 Bose et al.
6,607,539 B1 8/2003 Hayashi et al.
6,607,551 B1 8/2003 Sullivan et al.
6,613,074 B1 9/2003 Mitelberg et al.
6,613,075 B1 9/2003 Healy et al.
6,623,518 B2 9/2003 Thompson et al.
6,626,939 B1 9/2003 Burnside et al.
6,635,068 B1 10/2003 Dubrul et al.
6,638,243 B2 10/2003 Kupiecki
6,645,240 B2 11/2003 Yee
6,646,218 B1 11/2003 Campbell et al.
6,652,508 B2 11/2003 Griffin et al.
6,652,556 B1 11/2003 VanTassel et al.
6,656,212 B2 12/2003 Ravenscroft et al.
6,656,218 B1 12/2003 Denardo et al.
6,660,024 B1 12/2003 Flaherty et al.
6,663,666 B1 12/2003 Quiachon et al.
6,666,882 B1 12/2003 Bose et al.
6,669,719 B2 12/2003 Wallace et al.
6,669,721 B1 12/2003 Bose et al.
6,673,089 B1 1/2004 Yassour et al.
6,673,100 B2 1/2004 Diaz et al.
6,679,893 B1 1/2004 Tran
6,682,546 B2 1/2004 Amplatz
6,682,557 B1 1/2004 Quiachon et al.
6,685,735 B1 2/2004 Ahari
6,689,162 B1 2/2004 Thompson
6,689,486 B2 2/2004 Ho et al.
6,699,274 B2 3/2004 Stinson
6,709,454 B1 3/2004 Cox et al.
6,712,834 B2 3/2004 Yassour et al.
6,716,238 B2 4/2004 Elliott
6,726,700 B1 4/2004 Levine
6,730,108 B2 5/2004 Van Tassel et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,733,519 B2 5/2004 Lashinski et al.
6,740,105 B2 5/2004 Yodfat et al.
6,740,112 B2 5/2004 Yodfat et al.
6,743,219 B1 6/2004 Dwyer et al.
6,746,468 B1 6/2004 Sepetka et al.
6,746,890 B2 6/2004 Gupta et al.
6,755,855 B2 6/2004 Yurek et al.
6,758,885 B2 7/2004 Leffel et al.
6,767,361 B2 7/2004 Quiachon et al.
6,773,446 B1 8/2004 Dwyer et al.
6,780,196 B2 8/2004 Chin et al.
6,793,667 B2 9/2004 Hebert et al.
6,802,851 B2 10/2004 Jones et al.
6,811,560 B2 11/2004 Jones et al.
6,814,748 B1 11/2004 Baker et al.
6,818,006 B2 11/2004 Douk et al.
6,833,003 B2 12/2004 Jones et al.
6,849,084 B2 2/2005 Rabkin et al.
6,855,153 B2 2/2005 Saadat
6,858,034 B1 2/2005 Hijlkema et al.
6,860,893 B2 3/2005 Wallace et al.
6,860,898 B2 3/2005 Stack et al.
6,860,901 B1 3/2005 Baker et al.
6,866,677 B2 3/2005 Douk et al.
6,866,680 B2 3/2005 Yassour et al.
6,887,267 B2 5/2005 Dworschak et al.
6,890,337 B2 5/2005 Feeser et al.
6,936,055 B1 8/2005 Ken et al.
6,955,685 B2 10/2005 Escamilla et al.
6,960,227 B2 11/2005 Jones et al.
6,964,670 B1 11/2005 Shah et al.
6,976,991 B2 12/2005 Hebert et al.
6,989,024 B2 1/2006 Hebert et al.
6,994,092 B2 2/2006 van der Burg et al.
6,994,717 B2 2/2006 Konya et al.
6,994,721 B2 2/2006 Israel
7,001,422 B2 2/2006 Escamilla et al.
7,004,964 B2 2/2006 Thompson et al.
7,011,671 B2 3/2006 Welch
7,011,675 B2 3/2006 Hemerick et al.
7,029,487 B2 4/2006 Greene, Jr. et al.
7,037,330 B1 5/2006 Rivelli, Jr. et al.
7,066,951 B2 6/2006 Chobotov
7,069,835 B2 7/2006 Nishri et al.
7,074,236 B2 7/2006 Rabkin et al.
7,083,632 B2 8/2006 Avellanet et al.
7,093,527 B2 8/2006 Rapaport et al.
7,101,392 B2 9/2006 Heath
7,107,105 B2 9/2006 Bjorklund et al.
7,118,539 B2 10/2006 Vrba et al.
7,118,594 B2 10/2006 Quiachon et al.
7,122,050 B2 10/2006 Randall et al.
7,125,419 B2 10/2006 Sequin et al.
7,128,073 B1 10/2006 van der Burg et al.
7,128,736 B1 10/2006 Abrams et al.
7,137,990 B2 11/2006 Hebert et al.
7,166,125 B1 1/2007 Baker et al.
7,169,170 B2 1/2007 Widenhouse
7,169,172 B2 1/2007 Levine et al.
7,169,177 B2 1/2007 Obara
7,172,617 B2 2/2007 Colgan et al.
7,195,636 B2 3/2007 Avellanet et al.
7,195,639 B2 3/2007 Quiachon et al.
7,195,648 B2 3/2007 Jones et al.
7,201,768 B2 4/2007 Diaz et al.
7,201,769 B2 4/2007 Jones et al.
7,211,109 B2 5/2007 Thompson
7,213,495 B2 5/2007 McCullagh et al.
7,229,461 B2 6/2007 Chin et al.
7,232,461 B2 6/2007 Ramer
7,235,096 B1 6/2007 Van Tassel et al.
7,264,632 B2 9/2007 Wright et al.
7,275,471 B2 10/2007 Nishri et al.
7,279,005 B2 10/2007 Stinson
7,279,208 B1 10/2007 Goffena et al.
7,294,137 B2 11/2007 Rivelli, Jr. et al.
7,294,146 B2 11/2007 Chew et al.
7,300,456 B2 11/2007 Andreas et al.
7,300,460 B2 11/2007 Levine et al.
7,306,624 B2 12/2007 Yodfat et al.
7,309,351 B2 12/2007 Escamilla et al.
7,311,031 B2 12/2007 McCullagh et al.
7,320,702 B2 1/2008 Hammersmark et al.
7,331,973 B2 2/2008 Gesswein et al.
7,331,976 B2 2/2008 McGuckin, Jr. et al.
7,331,980 B2 2/2008 Dubrul et al.
7,331,985 B2 2/2008 Thompson et al.
7,338,518 B2 3/2008 Chobotov
7,419,503 B2 9/2008 Pulnev et al.
7,468,070 B2 12/2008 Henry et al.
7,470,282 B2 12/2008 Shelso
7,473,271 B2 1/2009 Gunderson
7,491,224 B2 2/2009 Cox et al.
7,578,826 B2 8/2009 Gandhi et al.
7,597,704 B2 10/2009 Frazier et al.
7,785,361 B2 * 8/2010 Nikolchev et al. 623/1.11
7,862,602 B2 1/2011 Licata et al.
8,114,154 B2 2/2012 Righini et al.
8,147,534 B2 4/2012 Berez et al.
8,192,480 B2 6/2012 Tieu et al.
8,206,431 B2 6/2012 Seppala et al.
8,236,042 B2 8/2012 Berez et al.
8,257,421 B2 9/2012 Berez et al.
8,267,985 B2 9/2012 Garcia et al.
8,273,101 B2 9/2012 Garcia et al.
2001/0000797 A1 5/2001 Mazzocchi
2001/0012949 A1 8/2001 Forber
2001/0012961 A1 8/2001 Deem et al.
2001/0049547 A1 12/2001 Moore
2002/0013618 A1 1/2002 Marotta et al.
2002/0062091 A1 5/2002 Jacobsen et al.
2002/0078808 A1 6/2002 Jacobsen et al.
2002/0087119 A1 7/2002 Parodi
2002/0099405 A1 7/2002 Yurek et al.
2002/0120323 A1 8/2002 Thompson et al.
2002/0143384 A1 10/2002 Ozasa
2002/0165572 A1 11/2002 Saadat
2002/0169473 A1 11/2002 Sepetka et al.
2002/0188341 A1 12/2002 Elliott
2003/0028209 A1 2/2003 Teoh et al.
2003/0057156 A1 3/2003 Peterson et al.
2003/0069522 A1 4/2003 Jacobsen et al.
2003/0100945 A1 5/2003 Yodfat et al.
2003/0109887 A1 6/2003 Galdonik et al.
2003/0135258 A1 7/2003 Andreas et al.
2003/0149465 A1 8/2003 Heidner et al.
2003/0163155 A1 8/2003 Haverkost et al.
2003/0163156 A1 8/2003 Hebert et al.
2003/0171739 A1 9/2003 Murphy et al.
2003/0195553 A1 10/2003 Wallace et al.
2003/0199913 A1 10/2003 Dubrul et al.
2003/0208256 A1 11/2003 DiMatteo et al.
2003/0216693 A1 11/2003 Mickley
2004/0024416 A1 2/2004 Yodfat et al.
2004/0044391 A1 3/2004 Porter
2004/0044395 A1 3/2004 Nelson
2004/0049204 A1 3/2004 Harari et al.
2004/0049256 A1 3/2004 Yee
2004/0059407 A1 3/2004 Escamilla et al.
2004/0073300 A1 4/2004 Chouinard et al.
2004/0078071 A1 4/2004 Escamilla et al.
2004/0093010 A1 5/2004 Gesswein et al.
2004/0093063 A1 * 5/2004 Wright et al. 623/1.12
2004/0122468 A1 6/2004 Yodfat et al.
2004/0127912 A1 * 7/2004 Rabkin et al. 606/108
2004/0138733 A1 7/2004 Weber et al.
2004/0143286 A1 7/2004 Johnson et al.
2004/0186551 A1 9/2004 Kao et al.
2004/0186562 A1 9/2004 Cox
2004/0193178 A1 9/2004 Nikolchev
2004/0193179 A1 9/2004 Nikolchev
2004/0193206 A1 9/2004 Gerberding et al.
2004/0199243 A1 10/2004 Yodfat
2004/0204749 A1 10/2004 Gunderson

(56) **References Cited**

U.S. PATENT DOCUMENTS

2004/0215332	A1	10/2004	Frid
2004/0220585	A1	11/2004	Nikolchev
2005/0010281	A1	1/2005	Yodfat et al.
2005/0033408	A1	2/2005	Jones et al.
2005/0033409	A1	2/2005	Burke et al.
2005/0049668	A1	3/2005	Jones et al.
2005/0049670	A1	3/2005	Jones et al.
2005/0090890	A1	4/2005	Wu et al.
2005/0096728	A1	5/2005	Ramer
2005/0096732	A1	5/2005	Marotta et al.
2005/0107823	A1	5/2005	Leone et al.
2005/0131523	A1	6/2005	Bashiri et al.
2005/0137680	A1	6/2005	Ortiz et al.
2005/0209672	A1	9/2005	George et al.
2005/0228434	A1	10/2005	Amplatz et al.
2005/0246010	A1	11/2005	Alexander et al.
2005/0267568	A1	12/2005	Berez et al.
2005/0283220	A1	12/2005	Gobran et al.
2005/0283222	A1	12/2005	Betelia et al.
2005/0288764	A1	12/2005	Snow et al.
2005/0288766	A1	12/2005	Plain et al.
2006/0036309	A1	2/2006	Hebert et al.
2006/0052815	A1	3/2006	Fitz et al.
2006/0052816	A1	3/2006	Bates et al.
2006/0058865	A1	3/2006	Case et al.
2006/0064151	A1	3/2006	Guterman et al.
2006/0089703	A1	4/2006	Escamilla et al.
2006/0095213	A1	5/2006	Escamilla et al.
2006/0111771	A1	5/2006	Ton et al.
2006/0116714	A1	6/2006	Sepetka et al.
2006/0116750	A1	6/2006	Hebert et al.
2006/0155323	A1	7/2006	Porter et al.
2006/0167494	A1	7/2006	Suddaby
2006/0184238	A1	8/2006	Kaufmann et al.
2006/0190076	A1	8/2006	Taheri
2006/0206200	A1	9/2006	Garcia et al.
2006/0206201	A1	9/2006	Garcia et al.
2006/0212127	A1	9/2006	Karabey et al.
2006/0235464	A1	10/2006	Avellanet et al.
2006/0235501	A1	10/2006	Igaki
2006/0247680	A1	11/2006	Amplatz et al.
2006/0271149	A1	11/2006	Berez et al.
2006/0271153	A1	11/2006	Garcia et al.
2007/0021816	A1	1/2007	Rudin
2007/0043419	A1	2/2007	Nikolchev et al.
2007/0055339	A1	3/2007	George et al.
2007/0073379	A1	3/2007	Chang
2007/0088387	A1	4/2007	Eskridge et al.
2007/0100414	A1	5/2007	Licata et al.
2007/0106311	A1	5/2007	Wallace et al.
2007/0112415	A1	5/2007	Bartlett
2007/0119295	A1	5/2007	McCullagh et al.
2007/0123969	A1	5/2007	Gianotti
2007/0162104	A1	7/2007	Frid
2007/0167980	A1	7/2007	Figulla et al.
2007/0191884	A1	8/2007	Eskridge et al.
2007/0198075	A1	8/2007	Levy
2007/0198076	A1	8/2007	Hebert et al.
2007/0203559	A1	8/2007	Freudenthal et al.
2007/0203563	A1	8/2007	Hebert et al.
2007/0203567	A1	8/2007	Levy
2007/0208376	A1	9/2007	Meng
2007/0221230	A1	9/2007	Thompson et al.
2007/0225760	A1	9/2007	Moszner et al.
2007/0225794	A1	9/2007	Thramann et al.
2007/0239261	A1	10/2007	Bose et al.
2007/0265656	A1	11/2007	Amplatz et al.
2007/0270902	A1	11/2007	Slazas et al.
2007/0288083	A1	12/2007	Hines
2007/0299500	A1	12/2007	Hebert et al.
2007/0299501	A1	12/2007	Hebert et al.
2007/0299502	A1	12/2007	Hebert et al.
2008/0003354	A1	1/2008	Nolan
2008/0021535	A1	1/2008	Leopold et al.
2008/0039933	A1	2/2008	Yodfat et al.
2008/0082154	A1	4/2008	Tseng et al.
2008/0097495	A1	4/2008	Feller, III et al.
2008/0119886	A1	5/2008	Greenhalgh et al.
2008/0154286	A1	6/2008	Abbott et al.
2008/0195139	A1	8/2008	Donald et al.
2008/0208320	A1	8/2008	Tan-Malecki et al.
2008/0219533	A1	9/2008	Grigorescu
2008/0221600	A1	9/2008	Dieck et al.
2008/0221666	A1*	9/2008	Licata et al. 623/1.22
2008/0255654	A1	10/2008	Hebert et al.
2008/0262590	A1	10/2008	Murray
2008/0269774	A1	10/2008	Garcia et al.
2008/0281350	A1	11/2008	Sepetka et al.
2008/0300667	A1	12/2008	Hebert et al.
2008/0319533	A1	12/2008	Lehe
2009/0024202	A1	1/2009	Dave et al.
2009/0024205	A1	1/2009	Hebert et al.
2009/0025820	A1	1/2009	Adams
2009/0030496	A1	1/2009	Kaufmann et al.
2009/0030497	A1	1/2009	Metcalf et al.
2009/0082803	A1	3/2009	Adams et al.
2009/0105802	A1	4/2009	Henry et al.
2009/0105803	A1	4/2009	Shelso
2009/0112251	A1	4/2009	Qian et al.
2009/0125093	A1	5/2009	Hansen
2009/0138065	A1	5/2009	Zhang et al.
2009/0163986	A1	6/2009	Tieu et al.
2009/0192536	A1	7/2009	Berez et al.
2009/0210047	A1	8/2009	Amplatz et al.
2009/0264978	A1	10/2009	Dieck et al.
2009/0270974	A1	10/2009	Berez et al.
2009/0275974	A1	11/2009	Marchand et al.
2009/0287241	A1	11/2009	Berez et al.
2009/0287288	A1	11/2009	Berez et al.
2009/0287292	A1	11/2009	Becking et al.
2009/0292348	A1	11/2009	Berez et al.
2009/0318947	A1	12/2009	Garcia et al.
2009/0319017	A1	12/2009	Berez et al.
2010/0030220	A1	2/2010	Truckai et al.
2010/0069948	A1	3/2010	Veznedaroglu et al.
2010/0152767	A1	6/2010	Greenhalgh et al.
2010/0268204	A1	10/2010	Tieu et al.
2010/0305606	A1	12/2010	Gandhi et al.
2010/0331948	A1	12/2010	Turovskiy et al.
2011/0313447	A1	12/2011	Strauss et al.
2012/0041470	A1	2/2012	Shrivastava et al.
2012/0041474	A1	2/2012	Eckhouse et al.
2012/0065720	A1	3/2012	Strauss et al.
2012/0221095	A1	8/2012	Berez et al.
2012/0277784	A1	11/2012	Berez et al.
2012/0283765	A1	11/2012	Berez et al.
2012/0283815	A1	11/2012	Berez et al.
2013/0144380	A1	6/2013	Quadri et al.
2013/0172976	A1	7/2013	Garcia et al.

FOREIGN PATENT DOCUMENTS

EP	696447	A2	2/1996
EP	1369098		12/2003
EP	1400219		3/2004
EP	1621148		2/2006
EP	2 143 404		1/2010
EP	2 143 460		1/2010
JP	10-328216	A	12/1998
JP	11-299901	A	11/1999
JP	2001-509412	A	7/2001
JP	2005-074230	A	3/2005
WO	WO-95/09586		4/1995
WO	WO-97/26939		7/1997
WO	WO-98/09583	A2	3/1998
WO	WO-99/02092		1/1999
WO	WO-99/03404		1/1999
WO	WO-99/05977		2/1999
WO	WO-99/49812		10/1999
WO	WO-99/62432		12/1999
WO	WO-00/13593		3/2000
WO	WO-01/05331		1/2001
WO	WO-01/93782		12/2001
WO	WO-02/00139		1/2002

(56) **References Cited**

FOREIGN PATENT DOCUMENTS

WO	WO-02/28320	A2	4/2002
WO	WO-02/056798	A2	7/2002
WO	WO-02/060345	A2	8/2002
WO	WO-02/071977	A2	9/2002
WO	WO-03/007840		1/2003
WO	WO-03/022124		3/2003
WO	WO-03/049600		6/2003
WO	WO-2004/010878	A1	2/2004
WO	WO-2004/030575		4/2004
WO	WO-2004/066809	A2	8/2004
WO	WO-2004/087006	A3	11/2004
WO	WO-2005/018728	A2	3/2005
WO	WO-2005/030093		4/2005
WO	WO-2005/115118		12/2005
WO	WO-2005/117718		12/2005
WO	WO-2006/026744		3/2006
WO	WO-2006/052322	A2	5/2006
WO	WO-2006/091891	A2	8/2006
WO	WO-2006/127005		11/2006
WO	WO-2007/121405		10/2007
WO	WO-2008/022327	A2	2/2008
WO	WO-2008/151204		12/2008
WO	WO-2008/157507	A2	12/2008
WO	WO-2009/134337		11/2009
WO	WO-2010/030991		3/2010
WO	WO-2011/130081	A1	10/2011

OTHER PUBLICATIONS

Ronen, "Amplatzer Vascular Plug Case Study, Closure of Arteriovenous Fistula Between Deep Femoral Artery and Superficial Femoral Vein," AGA Medical Corporation, May 2007.

Benndorf et al., "Treatment of ruptured dissecting vertebral artery anneurysm with double stent placement: case report," Am J Neuroradiol., Dec. 2001, vol. 22, No. 10, pp. 1844-1848.

Brilstra et al., Treatment of Intercranial Aneurysms by Emboloization with Coils: A Systematic Review, Stroke, 1999, vol. 30, pp. 470-476.

Ferguson, "Physical Factors in the Initiation, Growth and Rupture of Human Intracranial Saccular Aneurysms," J Neurosurg., 1972, vol. 37, pp. 666-677.

Geremia et al., "Embolization of experimentally created aneurysms with intravascular stent devices," Am J. Neuroradiol., Aug. 1994, vol. 15, No. 7, pp. 1223-1231.

Geremia et al., "Occlusion of experimentally created fusiform aneurysms with porous metallic stents," Am J Neuroradiol., Apr. 2000, vol. 4, pp. 739-745.

Lanzino et al., "Efficancy and current limitiations of intravascular stents for intracranial internal cartoid, vertebral, and basilar artery aneurysms," J Neurosurg., 1999, vol. 91, pp. 538-546.

Lieber et al, "The Physics of Endoluminal Stenting in the Treatment of Cerebrovascular Aneurysms," Neurological Research, 2002, vol. 24, Supplement 1, pp. S32-S42.

Lieber et al., "Alteration of Hemodynamics in Aneurysm Models by Stenting: Influence of Stent Porosity," Ann of Biomedical Eng., 1997, vol. 25, p. 460.

Moss, "Vascular Occulusion with a Balloon-Expandable Stent Occluder," Radiology, vol. 191, No. 2, May 1994, pp. 483-486.

Pereira, "History of Endovascular Aneurysms Occlusion in Management of Cerebral Aneurysms," Eds: Le Roux et al., 2004, pp. 11-26.

Qureshi, "Endovascular Treatment of Cerebrovascular Diseases and Intracranial Neoplasms," The Lancet, Mar. 2004, vol. 363, pp. 804-813.

Steiger, "Pathophysiology of Development and Rupture of Cerebral Aneurysms," Acta Neurochir Suppl., 1990, vol. 48, pp. 1-57.

Tenaglia, A. "Ultrasound Guide Wire-Directed Stent Deployment," Duke Univ. Medical Center, Department of Medicine, Am Heart J., 1993.

Yu et al., "A steady flow analysis on the stented and non-stented s dewall aneurysm models," Med Eng Phys., Apr. 1999, vol. 21, No. 3, 133-141.

* cited by examiner

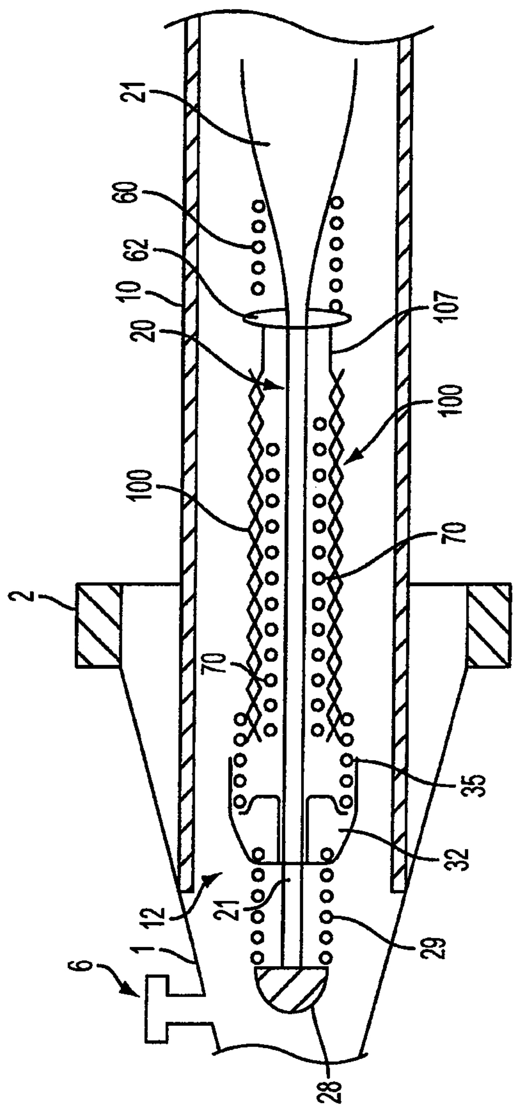


FIG. 1

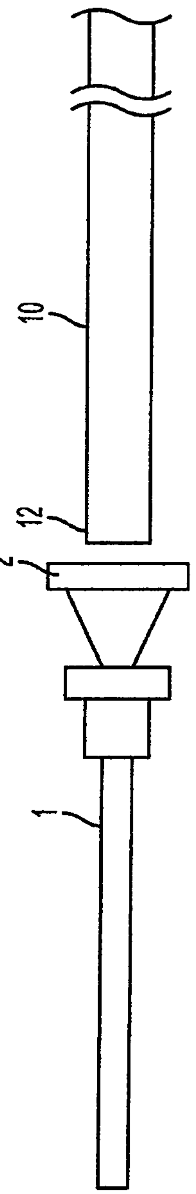
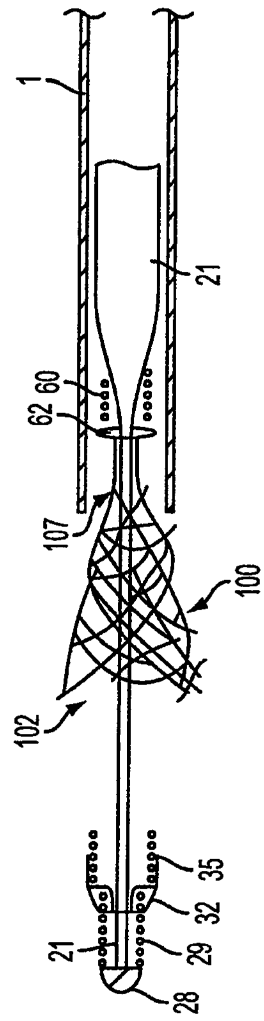


FIG. 2



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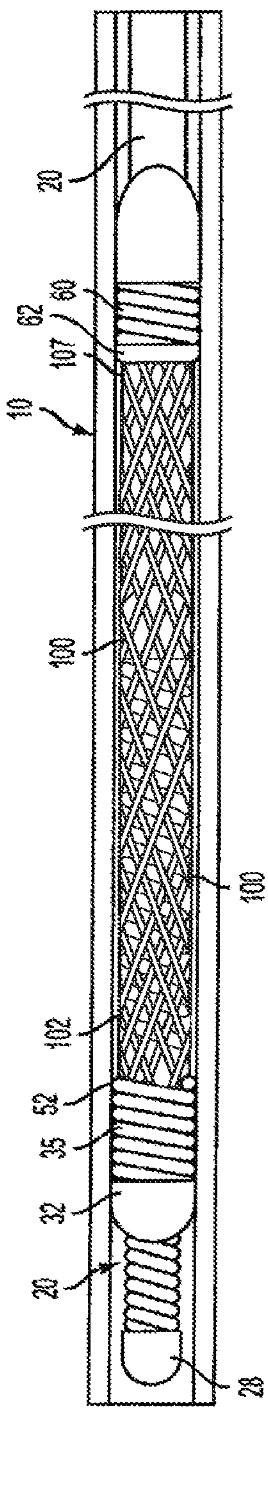


FIG. 3

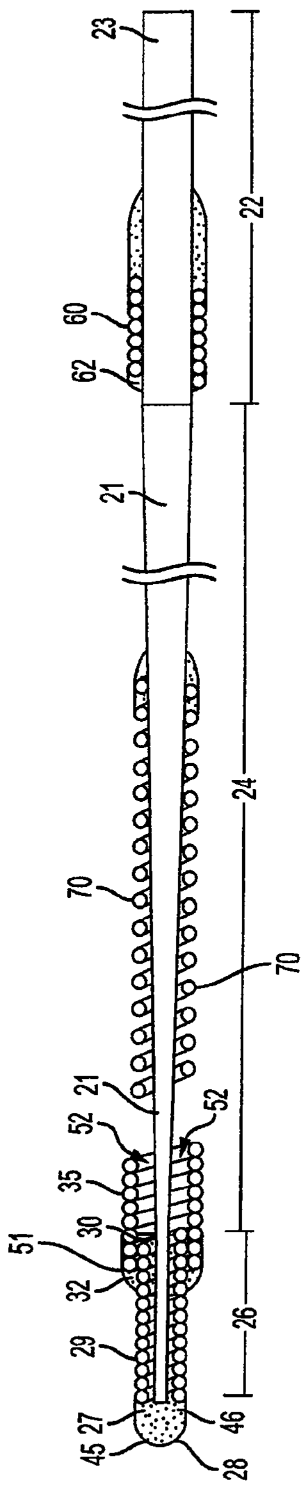


FIG. 4

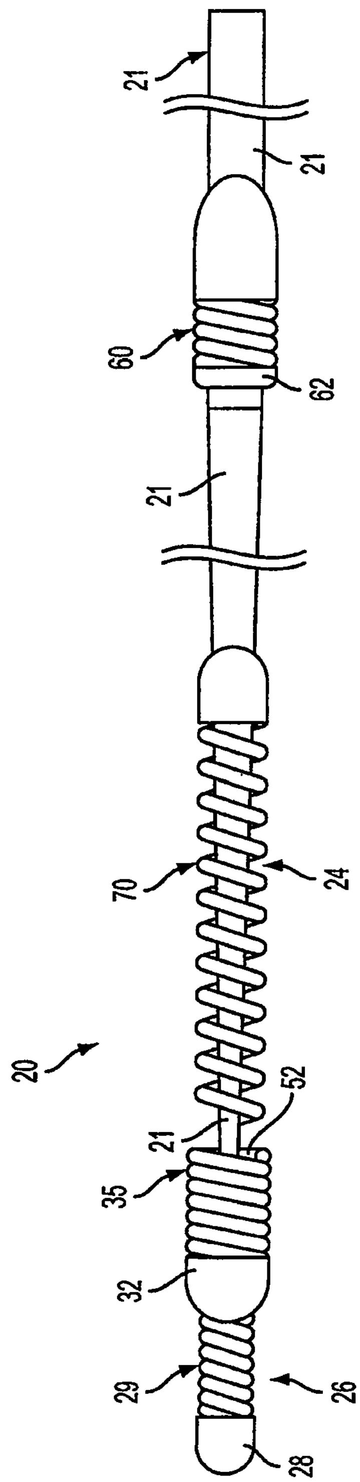


FIG. 5

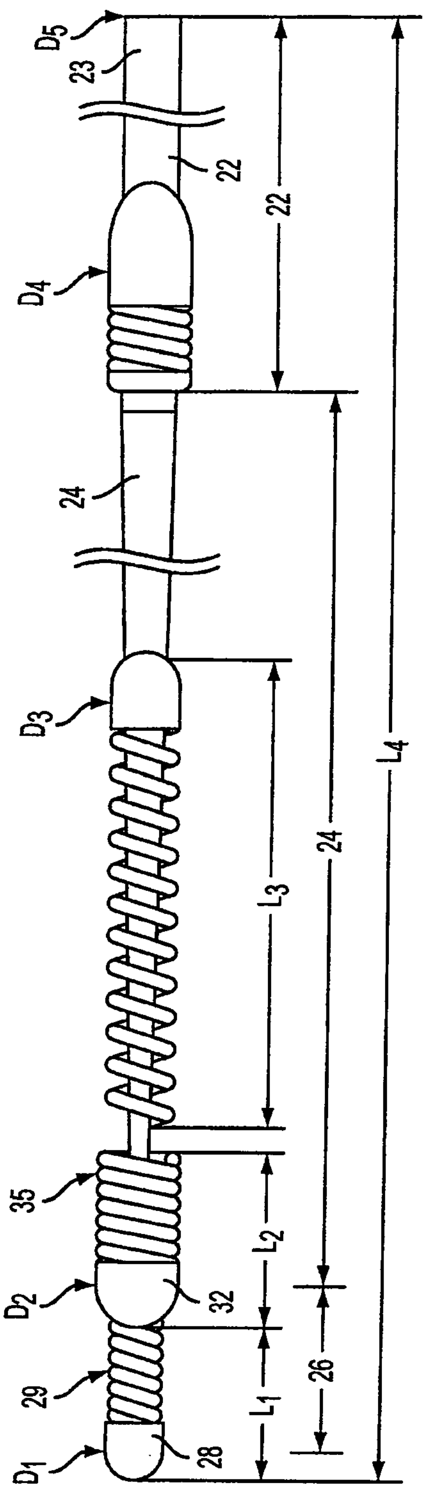


FIG. 6

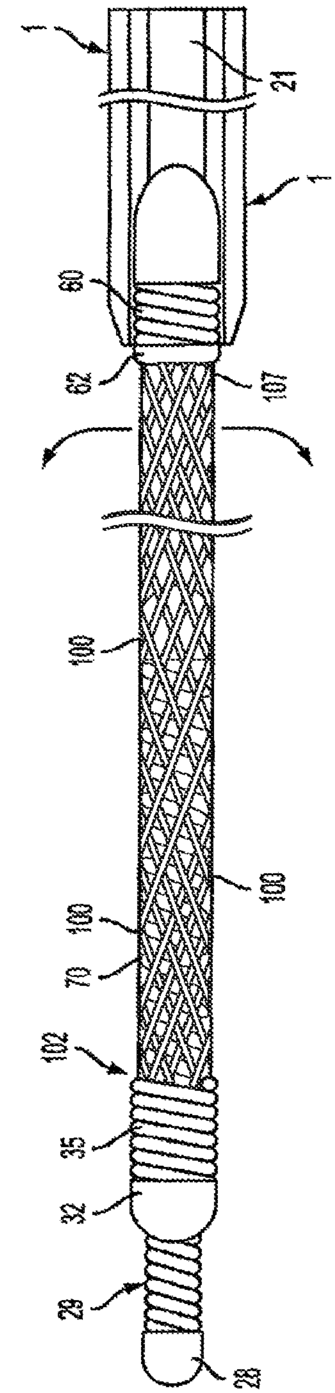


FIG. 7

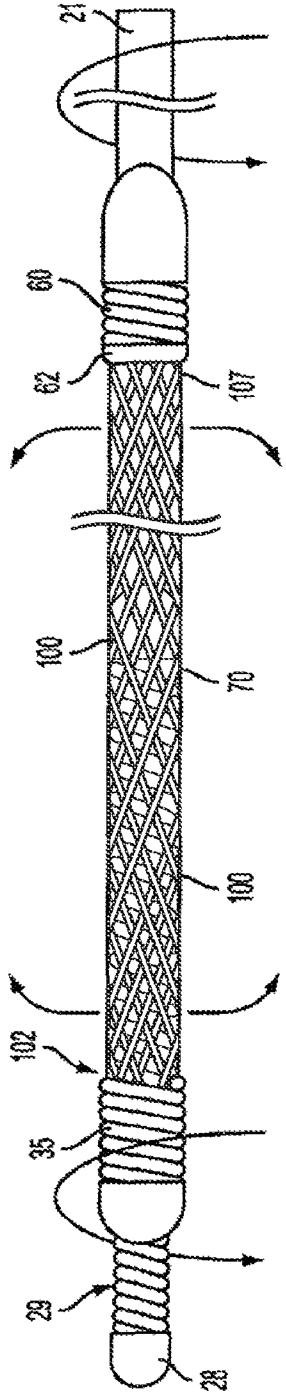
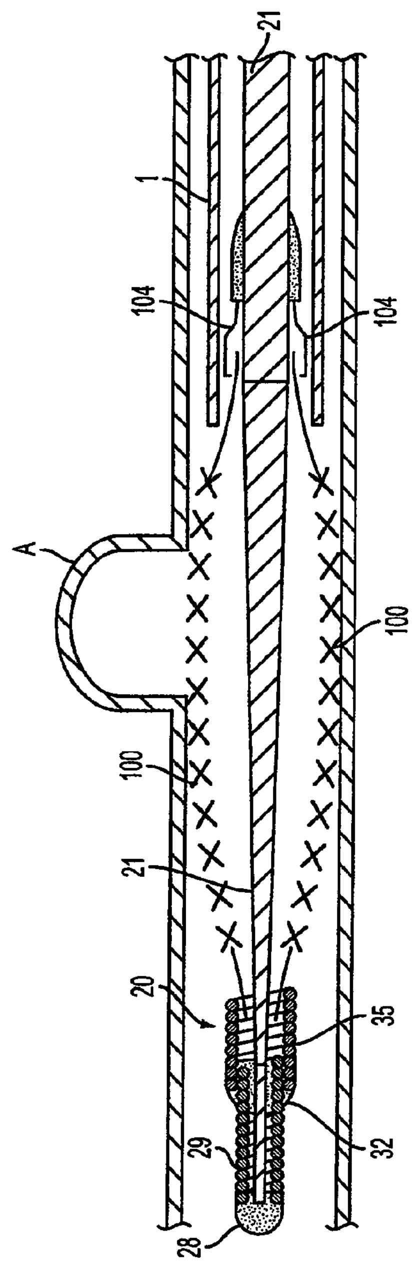


FIG. 8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1
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104
A
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100
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28

FIG. 10

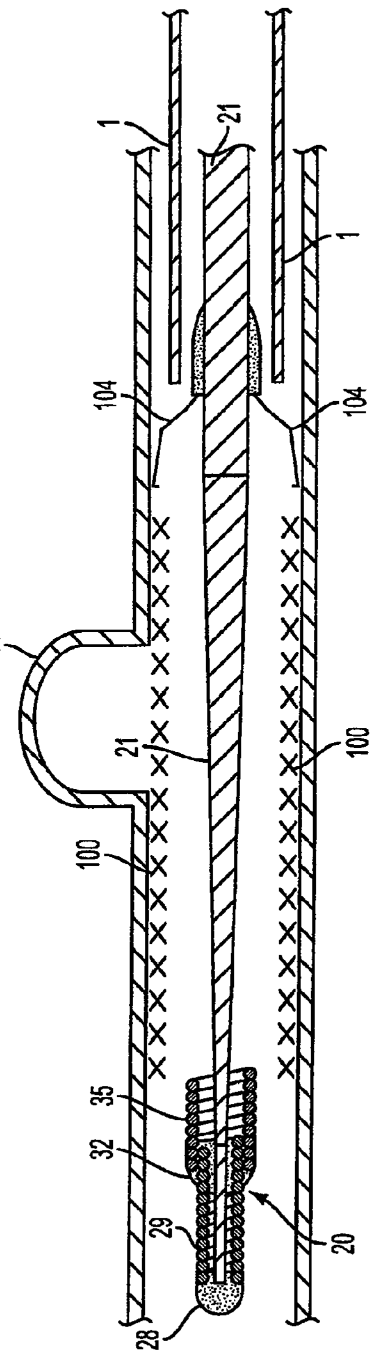
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FIG. 11

SYSTEM AND METHOD FOR DELIVERING AND DEPLOYING AN OCCLUDING DEVICE WITHIN A VESSEL

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 12/420,383, filed Apr. 8, 2009, which is a divisional of U.S. patent application Ser. No. 11/136,398, filed May 25, 2005, both of which are expressly incorporated herein by reference in their entireties.

FIELD

The invention generally relates to a system and method for delivering and deploying a medical device within a vessel, more particularly, it relates to a system and method for delivering and deploying an endoluminal therapeutic device within the vasculature of a patient to embolize and occlude aneurysms, particularly cerebral aneurysms.

BACKGROUND

Walls of the vasculature, particularly arterial walls, may develop areas of pathological dilatation called aneurysms. As is well known, aneurysms have thin, weak walls that are prone to rupturing. Aneurysms can be the result of the vessel wall being weakened by disease, injury or a congenital abnormality. Aneurysms could be found in different parts of the body with the most common being abdominal aortic aneurysms and brain or cerebral aneurysms in the neurovasculature. When the weakened wall of an aneurysm ruptures, it can result in death, especially if it is a cerebral aneurysm that ruptures.

Aneurysms are generally treated by excluding the weakened part of the vessel from the arterial circulation. For treating a cerebral aneurysm, such reinforcement is done in many ways including: (i) surgical clipping, where a metal clip is secured around the base of the aneurysm; (ii) packing the aneurysm with small, flexible wire coils (micro-coils); (iii) using embolic materials to "fill" an aneurysm; (iv) using detachable balloons or coils to occlude the parent vessel that supplies the aneurysm; and (v) intravascular stenting.

Intravascular stents are well known in the medical arts for the treatment of vascular stenoses or aneurysms. Stents are prostheses that expand radially or otherwise within a vessel or lumen to provide support against the collapse of the vessel. Methods for delivering these intravascular stents are also well known.

In conventional methods of introducing a compressed stent into a vessel and positioning it within in an area of stenosis or an aneurysm, a guiding catheter having a distal tip is percutaneously introduced into the vascular system of a patient. The guiding catheter is advanced within the vessel until its distal tip is proximate the stenosis or aneurysm. A guidewire positioned within an inner lumen of a second, inner catheter and the inner catheter are advanced through the distal end of the guiding catheter. The guidewire is then advanced out of the distal end of the guiding catheter into the vessel until the distal portion of the guidewire carrying the compressed stent is positioned at the point of the lesion within the vessel. Once the compressed stent is located at the lesion, the stent may be released and expanded so that it supports the vessel.

SUMMARY

Aspects of the present invention include a system and method of deploying an occluding device within a vessel. The

occluding device can be used to remodel an aneurysm within the vessel by, for example, neck reconstruction or balloon remodeling. The occluding device can be used to form a barrier that retains occlusion material such as a well known coil or viscous fluids, such as "ONYX" by Microtherapeutics, within the aneurysm so that introduced material will not escape from within the aneurysm. Also, during deployment, the length of the occluding device can be adjusted in response to friction created between the occluding device and an inner surface of a catheter. When this occurs, the deployed length and circumferential size of the occluding device can be changed as desired by the physician performing the procedure.

An aspect of the present invention includes a system for supporting and deploying an occluding device. The system comprises an introducer sheath and an assembly for carrying the occluding device. The assembly includes an elongated flexible member having an occluding device retaining member for receiving a first end of the occluding device, a proximally positioned retaining member for engaging a second end of the occluding device and a support surrounding a portion of the elongated flexible member over which the occluding device can be positioned.

Another aspect of the present invention includes a system for supporting and deploying an occluding device. The system comprises an assembly for carrying the occluding device. The assembly comprises an elongated member including a flexible distal tip portion, a retaining member for receiving a first end of the occluding device, and a support surrounding a portion of the elongated flexible member for supporting the occluding device.

A further aspect of the present invention comprises a method of introducing and deploying an occluding device within a vessel. The method includes the steps of introducing an elongated sheath including an introducer sheath carrying a guidewire assembly into a catheter and advancing the guidewire assembly out of the sheath and into the catheter. The method also includes the steps of positioning an end of the catheter proximate an aneurysm, advancing a portion of the guidewire assembly out of the catheter and rotating a portion of the guidewire assembly while deploying the occluding device in the area of the aneurysm.

BRIEF DESCRIPTION OF THE FIGURES

FIG. **1** is a cross section of an occluding device delivery assembly and occluding device according to an aspect of the invention;

FIG. **2** illustrates a catheter and introducer sheath shown in FIG. **1**;

FIG. **3** is a partial cut away view of the introducer sheath of FIG. **2** carrying a guidewire assembly loaded with an occluding device;

FIG. **4** is a cross section of the guidewire assembly illustrated in FIG. **3**;

FIG. **5** is a schematic view of the guidewire assembly of FIG. **4**;

FIG. **6** is a second schematic view of the guidewire assembly of FIG. **4**;

FIG. **7** illustrates the occluding device and a portion of the guidewire assembly positioned outside the catheter, and how a proximal end of the occluding device begins to deploy within a vessel;

FIG. **8** illustrates a step in the method of deploying the occluding device;

FIG. **9** illustrates the deployment of the occluding device according to an aspect of the present invention;

FIG. **10** is a schematic view of a guidewire assembly according to another embodiment of the present invention; and

FIG. **11** is a schematic view of the deployed occluding device after having been deployed by the guidewire assembly of FIG. **10**.

DETAILED DESCRIPTION

An occluding device delivery assembly having portions with small cross section(s) and which is highly flexible is described herein. FIG. **1** illustrates an introducer sheath **10** according to an aspect of the present invention that receives, contains and delivers an occluding device **100** to a flexible micro-catheter **1** for positioning within the vasculature of an individual. The occluding device **100** can include those embodiments disclosed in copending U.S. patent application Ser. No. 11/136,395, titled "Flexible Vascular Occluding Device", filed on May 25, 2005, which is expressly hereby incorporated by reference in its entirety.

A distal end **12** of the introducer sheath **10** is sized and configured to be received within a hub **2** of the micro-catheter **1**, as shown in FIGS. **1** and **2**. The hub **2** can be positioned at the proximal end of the micro-catheter **1** or at another location spaced along the length of the micro-catheter **1**. The micro-catheter **1** can be any known micro-catheter that can be introduced and advanced through the vasculature of a patient. In an embodiment, the micro-catheter has an inner diameter of 0.047 inch or less. In another embodiment, the micro-catheter has an inner diameter of about 0.027 inch to about 0.021 inch. In an alternative embodiment, the micro-catheter could have an inner diameter of about 0.025 inch. However, it is contemplated that the catheter **1** can have an inner diameter that is greater than 0.047 inch or less than 0.021 inch. After the introducer sheath **10** is positioned within the catheter hub **2**, the occluding device **100** can be advanced from the introducer sheath **10** into the micro-catheter **1** in preparation for deploying the occluding device **100** within the vasculature of the patient.

The micro-catheter **1** may have at least one fluid introduction port **6** located adjacent the hub **2** or at another position along its length. The port **6** is preferably in fluid communication with the distal end of the micro-catheter **1** so that a fluid, e.g., saline, may be passed through the micro-catheter **1** prior to insertion into the vasculature for flushing out air or debris trapped within the micro-catheter **1** and any instruments, such as guidewires, positioned within the micro-catheter **1**. The port **6** may also be used to deliver drugs or fluids within the vasculature as desired.

FIG. **3** illustrates the introducer sheath **10**, an elongated flexible delivery guidewire assembly **20** that is movable within the introducer sheath **10** and the occluding device **100**. As shown, the guidewire assembly **20** and the occluding device **100**, carried by the guidewire assembly **20**, have not been introduced into the micro-catheter **1**. Instead, as illustrated, they are positioned within the introducer sheath **10**. The introducer sheath **10** may be made from various thermoplastics, e.g., PTFE, FEP, HDPE, PEEK, etc., which may optionally be lined on the inner surface of the sheath or an adjacent surface with a hydrophilic material such as PVP or some other plastic coating. Additionally, either surface may be coated with various combinations of different materials, depending upon the desired results.

The introducer sheath **10** may include drainage ports or purge holes (not shown) formed into the wall near the area covering the occluding device **100**. There may be a single hole or multiple holes, e.g., three holes, formed into introducer sheath **10**. These purge holes allow for fluids, e.g., saline, to readily escape from in between the introducer sheath **10** and the guidewire assembly **20** when purging the sheath prior to positioning the introducer sheath **10** in contact with the catheter hub **2**, e.g., to remove trapped air or debris.

As shown in FIG. **4**, the guidewire assembly **20** includes an elongated flexible guidewire **21**. The flexibility of the guidewire **21** allows the guidewire assembly to bend and conform to the curvature of the vasculature as needed for positional movement of the occluding device **100** within the vasculature. The guidewire **21** may be made of a conventional guidewire material and have a solid cross section. Alternatively, the guidewire **21** can be formed from a hypotube. In either embodiment, the guidewire **21** has a diameter D_5 ranging from about 0.010 inch to about 0.020 inch. In an embodiment, the largest diameter of the guidewire is about 0.016 inch. The material used for the guidewire **21** can be any of the known guidewire materials including superelastic metals, e.g., Nitinol. Alternatively, the guidewire **21** can be formed of metals such as stainless steel. Length L_4 of the guidewire can be from about 125 to about 190 cm. In an embodiment, the length L_4 is about 175 cm.

The guidewire assembly **20** can have the same degree of flexion along its entire length. In an alternative embodiment, the guidewire assembly **20** can have longitudinal sections, each with differing degrees of flexion/stiffness. The different degrees of flexions for the guidewire assembly **20** can be created using different materials and/or thicknesses within different longitudinal sections of the guidewire **21**. In another embodiment, the flexion of the guidewire **21** can be controlled by spaced cuts (not shown) formed within the delivery guidewire **21**. These cuts can be longitudinally and/or circumferentially spaced from each other. The cuts can be formed with precision within the delivery guidewire **21**. Different sections of the delivery guidewire **21** can include cuts formed with different spacing and different depths to provide these distinct sections with different amounts of flexion and stiffness. In any of the above embodiments, the guidewire assembly **20** and the guidewire **21** are responsive to torque applied to the guidewire assembly **20** by the operator. As discussed below, the torque applied to the guidewire assembly **20** via the guidewire **21** can be used to release the occluding device **100** from the guidewire assembly **20**.

The size and shape of the cuts formed within the delivery guidewire **21** may be controlled so as to provide greater or lesser amounts of flexibility. Because the cuts can be varied in width without changing the depth or overall shape of the cut, the flexibility of the delivery guidewire **21** may be selectively altered without affecting the torsional strength of the delivery guidewire **21**. Thus, the flexibility and torsional strength of the delivery guidewire **21** may be selectively and independently altered.

Advantageously, longitudinally adjacent pairs of cuts may be rotated about 90 degrees around the circumference of the delivery guidewire **21** from one another to provide flexure laterally and vertically. However, the cuts may be located at predetermined locations to provide preferential flexure in one or more desired directions. Of course, the cuts could be randomly formed to allow bending (flexion) equally, non-preferentially in all directions or planes. In one embodiment, this could be achieved by circumferentially spacing the cuts.

The flexible delivery guidewire **21** can include any number of sections having the same or differing degrees of flexion. For example, the flexible delivery guidewire **21** could include two or more sections. In the embodiment illustrated in FIG. **4**, the flexible delivery guidewire **21** includes three sections, each having a different diameter. Each section can have a diameter of about 0.005 inch to about 0.025 inch. In an embodiment, the diameter of one or more sections can be about 0.010 inch to about 0.020 inch. A first section **22** includes a proximal end **23** that is located opposite the position of the occluding device **100**. The first section **22** can have a constant thickness along its length. Alternatively, the first section **22** can have a thickness (diameter) that tapers along its entire length or only a portion of its length. In the tapered embodiment, the thickness (diameter) of the first section **22** decreases in the direction of a second, transition section **24**. For those embodiments in which the guidewire **21** has a circular cross section, the thickness is the diameter of the section.

The second, transition section **24** extends between the first section **22** and a third, distal section **26**. The second section **24** tapers in thickness from the large diameter of the first section **22** to the smaller diameter of the third section **26**. As with the first section **22**, the second section **24** can taper along its entire length or only a portion of its length.

The third section **26** has a smaller thickness compared to the other sections **22**, **24** of the delivery guidewire **21**. The third section **26** extends, away from the tapered second section **24** that carries the occluding device **100**. The third section **26** can taper along its entire length from the second section **24** to the distal end **27** of the delivery guidewire **21**. Alternatively, the third section **26** can have a constant diameter or taper along only a portion of its length. In such an embodiment, the tapering portion of the third section **26** can extend from the second section **24** or a point spaced from the second section **24** to a point spaced from distal end **27** of the delivery guidewire **21**. Although three sections of the delivery guidewire **21** are discussed and illustrated, the delivery guidewire **21** can include more than three sections. Additionally, each of these sections can taper in their thickness (diameter) along all or only a portion of their length. In any of the disclosed embodiments, the delivery guidewire **21** can be formed of a shape memory alloy such as Nitinol.

A tip **28** and flexible tip coil **29** are secured to the distal end **27** of the delivery guidewire **21** as shown in FIGS. **4** and **5**. The tip **28** can include a continuous end cap or cover as shown in the figures, which securely receives a distal end of the tip coil **29**. Flexion control is provided to the distal end portion of the delivery guidewire **21** by the tip coil **29**. However, in an embodiment, the tip **28** can be free of the coil **29**. The tip **28** has a non-percutaneous, atraumatic end face. In the illustrated embodiment, the tip **28** has a rounded face. In alternative embodiments, the tip **28** can have other non-percutaneous shapes that will not injure the vessel in which it is introduced. As illustrated in FIG. **4**, the tip **28** includes a housing **45** that securely receives the distal end of the guidewire **21** within an opening **46** in the interior surface of the housing **45**. The guidewire **21** can be secured within the opening by any known means.

As shown in FIG. **4**, the tip coil **29** surrounds a portion of the guidewire **21**. The tip coil **29** is flexible so that it will conform to and follow the path of a vessel within the patient as the tip **28** is advanced along the vessel and the guidewire **21** bends to follow the tortuous path of the vasculature. The tip coil **29** extends rearward from the tip **28** in the direction of the proximal end **23**, as shown.

The tip **28** and coil **29** have an outer diameter D_1 of about 0.010 inch to about 0.018 inch. In an embodiment, their outer diameter D_1 is about 0.014 inch. The tip **28** and coil **29** also have a length L_1 of about 0.1 cm to about 3.0 cm. In an embodiment, they have a total length L_1 of about 1.5 cm.

A proximal end **30** of the tip coil **29** is received within a housing **32** at a distal end **24** of a protective coil **35**, as shown in FIGS. **1** and **4**. The housing **32** and protective coil **35** have an outer diameter D2 of about 0.018 inch to about 0.038 inch. In an embodiment, their outer diameter D_2 is about 0.024 inch. The housing **32** and protective coil **35** have a length L2 of about 0.05 cm to about 0.2 cm. In an embodiment, their total length L2 is about 0.15 cm.

The housing **32** has a non-percutaneous, atraumatic shape. For example, as shown in FIG. **5**, the housing **32** has a substantially blunt profile. Also, the housing **32** can be sized to open/support the vessel as it passes through it. Additionally, the housing **32** can include angled sidewalls sized to just be spaced just off the inner surface of the introducer sheath **10**.

The housing **32** and protective coil **35** form a distal retaining member that maintains the position of the occluding device **100** on the flexible guidewire assembly **20** and helps to hold the occluding device **100** in a compressed state prior to its delivery and deployment within a vessel of the vasculature. The protective coil **35** extends from the housing **32** in the direction of the proximal end **23** of the delivery guidewire **21**, as shown in FIG. **4**. The protective coil **35** is secured to the housing **32** in any known manner. In a first embodiment, the protective coil **35** can be secured to the outer surface of the housing **32**. In an alternative embodiment, the protective coil **35** can be secured within an opening of the housing **32** so that the housing **32** surrounds and internally receives the distal end **51** of the protective coil **35** (FIG. **4**). As shown in FIGS. **3** and **4**, the distal end **102** of the occluding device **100** is retained within the proximal end **52** so that the occluding device **100** cannot deploy while positioned in the sheath **10** or the micro-catheter **1**.

At the proximal end of the occluding device **100**, a bumper coil **60** and cap **62** prevent lateral movement of the occluding device **100** along the length of the guidewire **21** in the direction of the proximal end **23**, see FIG. **3**. The bumper coil **60** and cap **62** have an outer diameter D_4 of about 0.018 inch to about 0.038 inch. In an embodiment, their outer diameter D_4 is about 0.024 inch. The cap **62** contacts the proximal end **107** of the occluding device **100** and prevents it from moving along the length of the guidewire **21** away from the protective coil **35**. The bumper coil **60** can be in the form of a spring that contacts and pressures the cap **62** in the direction of the protective coil **35**, thereby creating a biasing force against the occluding device **100**. This biasing force (pressure) aids in maintaining the secured, covered relationship between the distal end **102** of the occluding device **100** and the protective coil **35**. As with any of the coils positioned along the delivery guidewire **21**, the bumper coil **60** can be secured, to the delivery guidewire **21** by soldering, welding, RF welding, glue, and/or other known adhesives.

In an alternative embodiment illustrated in FIG. **10**, the bumper coil **60** is not utilized. Instead, a proximal end **107** of the occluding device **100** is held in position by a set of spring loaded arms (jaws) **104** while positioned within the introducer sheath **10** or the micro-catheter **1**. The inner surfaces of the micro-catheter **1** and the introducer sheath **10** limit the radial expansion of the arms **104**. When the proximal end of the occluding device passes out of the micro-catheter **1**, the arms **104** would spring open and release the occluding device as shown in FIG. **11**.

In an alternative embodiment, the bumper coil **60** and cap **62** can be eliminated and the proximal end of the occluding device **100** can be held in position relative to the protective coil **35** by a tapered section of the guidewire **21**. In such an embodiment, the enlarged cross section of this tapered section can be used to retain the occluding device **100** in position along the length of the delivery guidewire **21** and prevent movement of the occluding device **100** in the direction of the proximal end **23**.

As shown in FIG. **4**, the guidewire assembly **20** includes a support **70** for the occluding device **100**. In a first embodiment, the support **70** can include an outer surface of the delivery guidewire **21** that is sized to contact the inner surface of the occluding device **100** when the occluding device **100** is loaded on the guidewire assembly **20**. In this embodiment, the outer surface of the delivery guidewire **21** supports the occluding device **100** and maintains it in a ready to deploy state. In another embodiment, illustrated in the Figures, the support **70** comprises a mid-coil **70** that extends from a location proximate the protective coil **35** rearward toward the bumper coil **60**. The mid-coil **70** extends under the occluding device **100** and over the delivery guidewire **21**, as shown in FIG. **1**. The mid-coil **70** can be coextensive with one or more sections of the delivery guidewire **21**. For example, the mid-coil **70** could be coextensive with only the second section **24** of the delivery guidewire **21** or it could extend along portions of both the third section **26** and the second section **24** of the delivery guidewire **21**.

The mid-coil **70** provides the guidewire assembly **20** with an outwardly extending surface that is sized to contact the inner surface of the occluding device **100** in order to assist in supporting the occluding device and maintaining the occluding device **100** in a ready to deploy state. Like the other coils discussed herein and illustrated in the figures, the coiled form of the mid-coil **70** permits the mid-coil **70** to flex with the delivery guidewire **21** as the delivery guidewire **21** is advanced through the vasculature of the patient. The mid-coil **70** provides a constant diameter along a length of the delivery guidewire **21** that is covered by the occluding device **100** regardless of the taper of the delivery guidewire **21** beneath the occluding device **100**. The mid-coil **70** permits the delivery guidewire **21** to be tapered so it can achieve the needed flexibility to follow the path of the vasculature without compromising the support provided to the occluding device **100**. The mid-coil **70** provides the occluding device **100** with constant support regardless of the taper of the delivery guidewire **21** prior to the occluding device **100** being deployed. The smallest diameter of the occluding device **100** when in its compressed state is also controlled by the size of the mid-coil **70**. Additionally, the diameter of the mid-coil **70** can be chosen so that the proper spacing, including no spacing, is established between the occluding device **100** and the inner wall of the micro-catheter **1** prior to deployment of the occluding device **100**. The mid-coil **70** can also be used to bias the occluding device **100** away from the delivery guidewire **21** during its deployment.

In either embodiment, the support **70** can have an outer diameter D_3 of about 0.010 inch to about 0.018 inch. In an embodiment, the outer diameter D_3 is about 0.014 inch. The support **70** can also have a length L_3 of about 2.0 cm to about 30 cm. In an embodiment, the length L_3 of the support **70** is about 7 cm.

The occluding device **100** may also be placed on the mid-coil **70** between an optional pair of radio-opaque marker bands located along the length of the guidewire assembly **20**. Alternatively, the protective coil **35**, bumper coil **60** and or mid-coil **70** can include radio-opaque markers. In an alternative embodiment, the guidewire assembly **20** may include only a single radio-opaque marker. The use of radio-opaque markers allows for the visualization of the guidewire assembly **20** and the occluding device **100** during placement within the vasculature. Such visualization techniques may include conventional methods such as fluoroscopy, radiography, ultra-sonography, magnetic resonance imaging, etc.

The occluding device **100** can be delivered and deployed at the site of an aneurysm A according to the following method and variations thereof. The delivery of the occluding device **100** includes introducing the micro-catheter **1** into the vasculature until it reaches a site that requires treatment. The micro-catheter **1** is introduced into the vasculature using a conventional technique such as being advanced over or simultaneously with a conventional vascular guidewire (not shown). The positioning of the micro-catheter **1** can occur before it receives the guidewire assembly **20** or while it contains the guidewire assembly **20**. The position of the micro-catheter **1** within the vasculature can be determined by identifying radio-opaque markers positioned on or in the micro-catheter **1**.

After the micro-catheter **1** is positioned at the desired location, the guidewire is removed and the distal end of the introducer sheath **10** is inserted into the proximal end of the micro-catheter **1**, as shown in FIG. **1**. In an embodiment, the distal end of the introducer sheath **10** is introduced through the hub **2** at the proximal end of the micro-catheter **1**. The introducer sheath **10** is advanced within the micro-catheter **1** until a distal tip of the introducer sheath **10** is wedged within the micro-catheter **1**. At this position, the introducer sheath **10** cannot be advanced further within the micro-catheter **1**. The introducer sheath **10** is then securely held while the delivery guidewire assembly **20** carrying the occluding device **100** is advanced through the introducer sheath **10** until the occluding device **100** is advanced out of the introducer sheath **10** and into the micro-catheter **1**.

The guidewire assembly **20** and the occluding device **100** are advanced through the micro-catheter **1** until the tip coil **29** is proximate the distal end of the micro-catheter **1**. At this point, the position of the micro-catheter **1** and guidewire assembly **20** can be confirmed. The guidewire assembly **20** is then advanced out of the micro-catheter **1** and into the vasculature of the patient so that the proximal end **107** of the occluding device **100** is positioned outside the distal end of the micro-catheter **1** and adjacent the area to be treated. At any point during these steps, the position of the occluding device **100** can be checked to determine that it will be deployed correctly and at the desired location. This can be accomplished by using the radio-opaque markers discussed above.

When the distal end **102** of the occluding device **100** is positioned outside the micro-catheter **1**, the proximal end **107** will begin to expand, in the direction of the arrows shown in FIG. **7**, within the vasculature while the distal end **102** remains covered by the protective coil **35**. When the occluding device **100** is in the proper position, the delivery guidewire **21** is rotated (See FIG. **8**) until the distal end **102** of the occluding device **100** moves away from the protective coil **35** and expands within the vasculature at the desired location. The delivery guidewire **21** can be rotated either clockwise or counter clockwise as needed to deploy the occluding device **100**. In an embodiment, the delivery guidewire **21** may be rotated, for example, between two and ten turns in either or both directions. In another example, the occluding device may be deployed by rotating the delivery guidewire **21** clockwise for less than five turns, for example, three to five turns. After the occluding device **100** has been deployed, the delivery guidewire **21** can be retracted into the micro-catheter **100** and removed form the body.

In an alternative or additional deployment step shown in FIG. **9**, friction between the occluding device **100** and inner surface of the micro-catheter **1** cause the distal end of the occluding device **100** to separate from the protective coil **35**.

The friction can be created by the opening of the occluding device **100** and/or the mid-coil **70** biasing the occluding device **100** toward the inner surface of the micro-catheter **1**. The friction between the micro-catheter **1** and the occluding device **100** will assist in the deployment of the occluding device **100**. In those instances when the occluding device **100** does not open and separate from the protective coil **35** during deployment, the friction between occluding device **100** and the inner surface of the micro-catheter **1** will cause the occluding device **100** to move away from the protective coil **35** as the delivery guidewire **21** and the micro-catheter **1** move relative to each other. The delivery guidewire **21** can then be rotated and the occluding device **100** deployed within the vessel.

After the occluding device **100** radially self-expands into gentle, but secure, contact with the walls of the vessel so as to occlude the neck of the aneurysm A, the micro-catheter **1** may be removed entirely from the body of the patient. Alternatively, the micro-catheter **1** may be left in position within vasculature to allow for the insertion of additional tools or the application of drugs near the treatment site.

Known materials can be used in the present invention. One common material that can be used with the occluding device **100** and the guidewire **21** is Nitinol, a nickel-titanium shape memory alloy, which can be formed and annealed, deformed at a low temperature, and recalled to its original shape with heating, such as when deployed at body temperature in the body. The radio-opaque markers can be formed of radio-opaque materials including metals, such as platinum, or doped plastics including bismuth or tungsten to aid in visualization.

The apparatus and methods discussed herein are not limited to the deployment and use within the vascular system but may include any number of further treatment applications. Other treatment sites may include areas or regions of the body such as organ bodies. Modification of each of the above-described apparatus and methods for carrying out the invention, and variations of aspects of the invention that are obvious to those of skill in the art are intended to be within the scope of the claims. Furthermore, no element, component or method step is intended to be dedicated to the public regardless of whether the element, component or method step is explicitly recited in the claims.

What is claimed:

1. A method for delivering a stent to a location within a vessel, said method comprising:
- introducing a delivery assembly into a catheter, the delivery assembly comprising (i) an elongate flexible member; and (ii) a retaining member, at a distal portion of the elongate member, having an inner lumen that extends around a circumference of the elongate member, the lumen receiving a first end of the stent to secure a portion of the stent in the retaining member;
- positioning the stent and a distal end of the catheter proximate an aneurysm within the vessel such that at least a portion of the stent is outside of the distal end of the catheter;
- rotating said retaining member relative to the stent, whereby the first end moves proximally relative to the retaining member and is disengaged from within the lumen while deploying said stent at the aneurysm.

2. The method according to claim **1**, further comprising the step of removing the delivery assembly from within the catheter.

3. The method according to claim **1**, further comprising the step of removing the catheter from within the vessel.

4. The method according to claim **1**, further comprising the step of confirming the position of said stent prior to deploying said stent.

5. The method according to claim **1**, wherein the stent is self-expanding.

6. The method according to claim **1**, wherein the retaining member comprises a protective coil.

7. The method according to claim **1**, further comprising limiting proximal movement of a second end of the stent along a length of the elongate member.

8. The method according to claim **1**, wherein the first end of the stent is biased radially outwardly against the retaining member.

9. The method according to claim **1**, wherein the delivery assembly further comprises a proximal member configured to limit proximal movement of a second end of the stent along a length of the flexible member, the method further comprising maintaining the retaining member and the proximal member substantially fixed axially with respect to each other while the stent is released from the lumen.

10. A method for positioning a self-expanding device at a treatment site in a vessel, the method comprising:
- introducing a catheter and a delivery assembly into the vessel, the delivery assembly comprising an elongate flexible member including a retaining member receiving a first end of the self-expanding device, the self-expanding device being concentrically within the retaining member and biased against a surface positioned about a lumen of the retaining member; and
- positioning the catheter and the delivery assembly such that the retaining member and at least a portion of the self-expanding device are outside a distal end of the catheter and such that a second end of the self-expanding device is expanded toward a wall of the vessel;
- rotating the retaining member so as to release the first end of the self-expanding device from the retaining member by moving the first end proximally relative to the retaining member.

11. The method according to claim **10**, wherein the treatment site comprises an aneurysm.

12. The method according to claim **10**, wherein the retaining member comprises a protective coil, and the self-expanding device is received within an interior of the protective coil.

13. The method according to claim **10**, further comprising removing the delivery assembly proximally through the catheter and leaving the self-expanding device in the vessel.

14. A method for delivering a self-expanding device in a body lumen, the method comprising:
- providing a delivery assembly positioned at least partially within an introducer sheath, the delivery assembly comprising an elongate flexible member and a retaining member at a distal portion of the delivery assembly, the elongate flexible member extending through the retaining member, the retaining member having a lumen therein extending around the elongate flexible member, the retaining member receiving a first end of the self-expanding device within the lumen, the self-expanding device being biased radially outward against the retaining member;
- advancing at least a portion of the delivery assembly through the introducer sheath and into a catheter;
- positioning the delivery assembly and the catheter at least partially within the body lumen such that the retaining member is outside a distal end of the catheter and at least a portion of the self-expanding device extends distal of

the distal end of the catheter and such that a second end of the self-expanding device is expanded toward a wall of the body lumen;

rotating the retaining member, whereby the first end moves proximally relative to the retaining member so as to release the first end from within the retaining member.

15. The method according to claim **14**, wherein the assembly further comprises a second retaining member receiving a second end of the self-expanding device, the method further comprising releasing the second end of the self-expanding device from the second retaining member.

16. The method according to claim **14**, wherein the retaining member comprises a protective coil, the self-expanding device received within an interior of the protective coil.

17. The method according to claim **14**, further comprising inserting a distal end of the introducer sheath into a proximal end of the catheter, and removing the introducer sheath from the catheter after advancing the delivery assembly through the introducer sheath into the catheter.

18. The method according to claim **14**, further comprising removing the delivery assembly proximally through the catheter and leaving the self-expanding device in the body lumen.

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